

5. 510(K) SUMMARY

FEB 27 2007

Submitter/Contact Name: Jeme Wallace

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Date Prepared: 12/08/06

Trade Name: COLLEAGUE, COLLEAGUE 3¹
COLLEAGUE CX, COLLEAGUE 3 CX¹
COLLEAGUE CXE, COLLEAGUE 3 CXE
COLLEAGUE CX to CXE Pump Upgrade Kit
COLLEAGUE 3 CX to 3 CXE Pump Upgrade Kit

Common Name: COLLEAGUE Volumetric Infusion Pump

Classification Name: Infusion Pump as defined in 21 CFR 880.5725

Class: II

Procode: 80 FRN

Equivalent Predicate: COLLEAGUE Volumetric Infusion Pump, currently marketed models: COLLEAGUE, COLLEAGUE CX, COLLEAGUE 3, COLLEAGUE 3 CX

Device Description: The COLLEAGUE Volumetric Infusion Pump product is a software controlled, electromechanical, large volumetric infusion pump that includes either one or three infusion

¹ COLLEAGUE pumps will be upgraded to include either COLLEAGUE GUARDIAN functionality (for COLLEAGUE and COLLEAGUE 3) or COLLEAGUE Enhanced GUARDIAN functionality (for COLLEAGUE CX and COLLEAGUE 3 CX).

channels. The COLLEAGUE Volumetric Infusion Pump product provides the necessary infusion therapy modes to deliver medications and solutions through a Baxter standard administration set. The pump uses a shuttle pumping mechanism to achieve flow. None of the pump device materials come in contact with the solution path.

The COLLEAGUE Volumetric Infusion Pump is designed to accept Baxter standard administration sets equipped with keyed slide clamps that are labeled as being COLLEAGUE pump compatible. The unidirectional slide clamp helps ensure proper set loading. The pump will accept a variety of currently marketed solution containers including flexible containers, glass bottles, and syringes (with an accessory adapter).

The pump is intended to operate primarily on AC power and is equipped with a rechargeable battery to facilitate use during transport.

The COLLEAGUE GUARDIAN feature is a configurable option that helps to reduce the potential for medication programming errors by allowing program limits to be pre-defined for labels in the pump's label library, including custom labels, based on hospital or care area protocols.

The COLLEAGUE GUARDIAN feature (Monochrome and CX devices) is available for dose mode programming only. The COLLEAGUE GUARDIAN feature allows the facility to set up labels for programming standard concentrations of a dose mode infusion.

The COLLEAGUE Enhanced GUARDIAN feature (CXE devices) is a configurable option that is available for both rate/volume and dose mode programming. The COLLEAGUE Enhanced GUARDIAN feature allows the facility to set up labels set up for programming non-standard concentrations of a dose mode infusion

(modifying the Drug Amount, Diluent Volume and/or Concentration from the default.

The COLLEAGUE Volumetric Infusion Pump supports the use of a proprietary software accessory; COLLEAGUE GUARDIAN Configuration Tool. The configuration tool supports the creation and maintenance of Personalities (custom feature set for individual care area or for specific therapies), as well as the clinical labels and parameters established by the hospital using the COLLEAGUE GUARDIAN dose error reduction software. This software accessory is not required to operate the pump.

The COLLEAGUE Volumetric Infusion Pump also supports the use of proprietary software accessory; COLLEAGUE DL2 Event History Download Software Application. The COLLEAGUE DL2 Event History Download Software Application is a service application that downloads the event history log. This software accessory is not required to operate the pump.

The COLLEAGUE Volumetric Infusion Pump has the ability to communicate externally via a data communications interface.

Indications for Use:

The COLLEAGUE Volumetric Infusion Pump is designed to meet the fluid delivery needs of today's healthcare environment. The COLLEAGUE pump is capable of delivering medications, solutions, parenteral nutrition, lipids, blood and blood components.

The COLLEAGUE pump is designed to deliver infusion therapies via clinically acceptable routes of administration, including intravenous, intra-arterial, epidural, and subcutaneous routes.

The COLLEAGUE pump is intended for use in a wide variety of patient care environments for adult, pediatric and neonatal patients. The COLLEAGUE pump facilitates the

delivery of routine and critical infusion therapies via continuous and intermittent delivery using primary and piggyback infusion modes.

The COLLEAGUE pump can be used in the following care areas:

- General Floor of the Hospital
- Critical / Intensive Care
- Neonatal Intensive Care
- Pediatric Care
- Labor / Delivery / Postpartum
- Operating Room / Anesthesia
- Post Anesthesia / Recovery
- Cardiac Catheterization Lab
- Emergency Room
- Ground Ambulance
- Hospice Facility
- Outpatient / Subacute Facilities
- Nursing Facilities
- Long Term Care / Rehabilitation Facilities
- Diagnostic Nuclear Medicine
- Oncology Floor
- Burn Unit / Trauma

Summary of Technological

Characteristics:

The technological features of the modified COLLEAGUE Volumetric Infusion Pump do not significantly differ from the previously cleared COLLEAGUE Volumetric Infusion Pump. The subject and predicate devices have the same fundamental technological characteristics regarding the operating principle, use of administration sets, materials, physical features, intended use, and performance.

Non-Clinical Testing:

Non-clinical testing associated with compliance and safety, software, and intended use claims were performed according to the Baxter Healthcare Corporation Product

Development Process. Human Factors evaluation and use scenario testing was performed under simulated use and environmental conditions utilizing clinical care personnel from hospital environments. All tests successfully passed the acceptance criteria.

Conclusions:

The upgrades to the COLLEAGUE Volumetric Infusion Pump have been verified against design requirements and validated against defined user needs and intended uses. This demonstrates that the device is at least as safe, as effective, and performs as well as or better than the predicate COLLEAGUE Volumetric Infusion Pump.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jeme Wallace
Associate Director, Global Regulatory Affairs
Baxter Healthcare, Incorporated
One Baxter Parkway
Deerfield, Illinois 60015-4633

FEB 27 2007

Re: K063696

Trade/Device Name:	COLLEAGUE Infusion Pump	(2M8151)
	COLLEAGUE 3 Infusion Pump	(2M8153)
	COLLEAGUE CX Infusion Pump	(2M8161)
	COLLEAGUE 3 CX Infusion Pump	(2M8163)
	COLLEAGUE CXE Infusion Pump	(2M9161)
	COLLEAGUE 3 CXE Infusion Pump	(2M9163)
	COLLEAGUE CXE Feature Kit	(2M8580)
	COLLEAGUE 3 CXE Feature Kit	(2M8583)

Regulation Number: 21 CFR 880.5725

Regulation Name: Infusion Pump

Regulatory Class: II

Product Code: FRN

Dated: December 9, 2006

Received: December 13, 2006

Dear Ms. Wallace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): New Traditional 510(k)

Device Name: COLLEAGUE Volumetric Infusion Pump

Indications for Use: The COLLEAGUE Volumetric Infusion Pump is capable of delivering medications, solutions, parenteral nutrition, lipids, blood and blood components.

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The COLLEAGUE pump can be used in the following care areas:

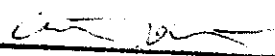
- General Floor of the Hospital
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- Pediatric Care
- Labor / Delivery / Postpartum
- Operating Room / Anesthesia
- Post Anesthesia / Recovery
- Cardiac Catheterization Lab
- Emergency Room
- Ground Ambulance
- Hospice Facility
- Outpatient / Subacute Facilities
- Nursing Facilities

- Long Term Care / Rehabilitation Facilities
- Diagnostic Nuclear Medicine
- Oncology Floor
- Burn Unit / Trauma

Table 1.

Prescription Use: <input checked="" type="checkbox"/>	Over the Counter Use: <input type="checkbox"/>
21 CFR 801 Subpart D	21 CFR Subpart C

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K467646